HACCP, Quality System Regulation, ISO 9001/13485 Comparison Chart

HACCP Principle	Quality Systems Regulation	ISO 9001/13485
1. **Conduct hazard analysis and identify preventive measures.**	❖ 820.30(g) - Design validation shall include. . . ***risk analysis***, where appropriate.	❖ 9001 4.4.8 Design validation ❖ 13485 4.4.1 General ❖ *13485 4.4.8 Design Validation*
	❖ 820.70(a) - Where deviations from device specification could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe ***any process controls necessary to ensure conformance to specifications.***	❖ 9001 4.9 (a)(c)(d)(e) and (f) Process control
	EXAMPLES OF PREVENTIVE MEASURES:	
	❖ **820.50 – Purchasing controls**	❖ 9001 4.6 Purchasing ❖ 9001 4.6.1 General
	❖ **820.80 – Receiving, in-process, and finished device acceptance**	❖ 9001 4.10 Inspection and testing
	❖ **820.86 – Acceptance status**	❖ 9001 4.12 Inspection and test status
	❖ **820.70(c) – Environmental controls**	❖ 9001 4.9(b) Process control ❖ 9001 4.11.2(g) Control procedure ❖ *13485 4.9(B) Environmental control in manufacture*
	❖ **820.70(d) – Personnel**	❖ 9001 4.9(b) Process control ❖ *13485 4.9(A) Personnel*
	❖ **820.70(e) – Contamination control**	❖ 9001 4.9(b) Process control ❖ *13485 4.9(C) Cleanliness of product*
	❖ **820.70(g) – Equipment maintenance**	❖ 9001 4.9(b) and (g) Process control ❖ *13485 4.9(D) Maintenance*
	❖ **820.72 – Inspection, measuring and test equipment**	❖ 9001 4.11 Control of inspection, measuring, and test equipment

2. **Identify Critical Control Points.**	❖ 820.30(g) - Design validation shall include. . . ***risk analysis***, where appropriate. ❖ 820.70(a) - Where deviations from device specification could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process ***control*** procedures that describe any ***process controls necessary to ensure conformance to specifications.***	❖ 9001 4.4.8 Design validation ❖ 13485 4.4.1 General ❖ *13485 4.4.8 Design Validation* ❖ 9001 4.9 (a)(c)(d)(e) and (f) Process control
3. **Establish critical limits.**	❖ 820.70(a) - Each manufacturer shall ***develop,*** conduct, control, and monitor ***production processes*** to ensure that a device conforms to its specifications. ❖ 820.70(a) – Where process controls are needed they shall include: (2) Monitoring and control of *process parameters* and *component and device characteristics* during production.	❖ 9001 4.9 (a)(c)(d)(e) and (f) Process control
4. **Monitor each critical control point.**	❖ 820.70(a) – Where process controls are needed they shall include: (2) ***Monitoring*** and control ***of process parameters and component and device characteristics*** during production.	❖ 9001 4.9 (a)(c)(d)(e) and (f) Process control
5. **Establish corrective action to be taken when deviation occurs.**	❖ 820.100(a) – Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (3) ***Identifying the actions(s) needed to correct and prevent recurrence of nonconforming product and other quality problems.***	❖ 9001 4.14 Corrective and preventive action ❖ *13485 4.14 Corrective and preventive action*

6. **Establish verification procedures.**	❖ 820.80 - Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other ***verification activities.***	❖ 9001 4.10 Inspection and testing
	❖ 820.100(a) – Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for: (4) ***Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device***;	❖ 9001 4.14 Corrective and preventive action ❖ *13485 4.14 Corrective and preventive action*
7. **Establish record-keeping system.**	❖ 820.70(a) - Where process controls are needed they shall include: (1) ***Documented instructions, standard operating procedures (SOPs) and methods*** that define and control the manner of production;	❖ 9001 4.9 (a)(c)(d)(e) and (f) Process control
	❖ 820.100(b) - ***All activities required under this section, and their results, shall be documented.***	❖ 9001 4.16 Control of quality records
	❖ 820.181 - Device master record	❖ 9001 4.2.2 Quality-system procedures ❖ 13485 4.2.3 Quality planning
	❖ 820.184 - Device history record	❖ 9001 4.16 Control of quality records ❖ *13485 4.16 Control of quality records*
	❖ 820.186 - Quality system record	❖ 9001 4.16 Control of quality records ❖ 9001 4.2.2 Quality-system procedures